JUN 16 2009

510(k) Summary

Contact:

Alyssa Thomas
Acumed, LLC
5885 NW Cornelius Pass Rd.
Hillsboro, OR 97124-9432
(503) 627-9957 x1294
FAX: (503) 686-7102

Device Trade Name: Acumed Clavicle Screw System

Manufacturer:

Acumed, LLC
5885 NW Cornelius Pass Rd.
Hillsboro, OR 97124-9432

Common Name: Pin, Fixation, Threaded

Classification: 21 CFR 888.3040

Class: II

Product Code: JDW

Indications for Use:
The Acumed Clavicle Screw System is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

Device Description:
The Acumed Clavicle Screw System includes screws with associated instruments to repair acute fractures, mal-unions or non-unions of the clavicle.

Technological Characteristics:
The screws are made of titanium alloy per ASTM F136. The screw is supplied in multiple diameters and multiple lengths. The predicate devices share these dimensional and material characteristics.

Performance Data:
A cadaver study using the Acumed Clavicle Screw was performed to help demonstrate substantial equivalence.

A discussion of clinical and non-clinical tests is not applicable.

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ACUMED® LLC 5885 NW Cornelius Pass Road, Hillsboro, OR 97124
Phone: (503) 627-9957 Fax: (503) 686-7102

Predicate Device(s):
DePuy Rockwood Clavicle Pin - K991649
True/Flex Clavicle Rod System - K934148
Hagie Pin - K903258
Steinmann, Knowles, and Hagie Pins - K863734
Herbert Bone Screw - K792022

Based upon the similarities of the Acumed Clavicle Screw System and the predicated devices studied, the safety and effectiveness of the Acumed Clavicle Screw System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acumed, LLC
% Ms. Alyssa Thomas
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

JUN 16 2009

Re: K083144
Trade/Device Name: Acumed Clavicle Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener accessories
Regulatory Class: II
Product Code: JDW
Dated: May 14, 2009
Received: May 18, 2009

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchner
for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083144

Device Name: Acumed Clavicle Screw System

Indications for Use:

The Acumed Clavicle Screw System is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083144